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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,901	01/26/2001	Joaquina Faour	PHUS-28	7749

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	13

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/770,901	Applicant(s) FAOUR ET AL.	
	Examiner Shaojia A. Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *9 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-38 and 40-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 24, 2002 in Paper No. 10 wherein claims 7, 8, 12-14, 16-18, 22-23, and 25-37 have been amended and claims 40-54 are newly submitted. Currently, claims 1-54 are pending in this application.

This application contains claims 9 and 39 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. 1-8,10-38 and 40-54

Applicant's amendment (amending claims 7-8 and 16-17) filed on January 24, 2002 in Paper No. 10 with respect to the objection to claims 7-8 and 16-17 for minor informalities, i.e., the employment of parenthetical expressions, of record stated in the Office Action dated September 28, 2001 has been fully considered and is found persuasive since claims 7-8 and 16-17 have been amended to remove these expressions. Therefore, this said objection is withdrawn.

Applicant's remarks and amendment (amending claim 25) filed on January 24, 2002 in Paper No. 10 with respect to the objection of claim 25 made under 37 CFR 1.75 (c) for improper dependent for failing to further limit claim 25 of record stated in the Office Action dated September 28, 2001 have been fully considered and are found persuasive. Therefore, this objection is withdrawn.

Applicant's amendment (amending claims 22-23) filed on January 24, 2002 in Paper No. 10 with respect to the rejection made under 35 U.S.C. 112 second paragraph for the indefinite expression "..one drug... the other drug " in claims 22-23 has been fully considered and found persuasive as to remove this particular rejection of claims 22-23.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-8, 12, 16-17, 18, 28-29, 31-37, and 40-48 are rejected under 35 U.S.C. 112, second paragraph, for indefinite expressions "slow or rapid release" in claim 12, "rapidly" in claim 18, "rapid, immediate.. slow, timed, delayed release.." in claim 29, and "rapid release" or "a delayed but rapid release" in claims 31-37, for reasons of record in the Office Action September 28, 2001.

Applicant's remarks filed on January 24, 2002 in Paper No. 10 with respect to this rejection have been fully considered but they are not deemed persuasive to remove the rejection. As discussed in the previous Office, these expressions are considered indefinite since they are relative terms. Note that the instant claims are not limited to the drug release profiles in the examples herein in the specification.

Claims 7-8, 16-17, and 40-48 still contain the trademark/trade name, e.g., SC-5766, SC-58215, and T-614. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte*

Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular active agents herein and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-38, and 40-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burch et al. essentially for reasons of record stated in the Office Action dated September 28, 2001.

Applicant's remarks filed on January 24, 2002 in Paper No. 10 and the declaration of Ethel C. Feleder under 37 C.F.R. 1.132 filed on January 24, 2002 in Paper No. 11 with respect to the rejection of claims 1-8 and 10-38 made under 35 U.S.C. 103(a) over Burch et al. have been fully considered but are not deemed

persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant argues that one of ordinary skill in the art would not necessarily have been motivated to employ a COX-II inhibitor in combination with a muscle relaxant in a pharmaceutical composition or dosage because drugs used in the same therapeutic area or even for treating the same indication cannot always be combined with the expectation of at least additive therapeutic effects. However, it has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06. In the instant case, as discussed in the set forth 103(a) rejection in the previous Office Action, COX-II inhibitors such as rofecoxib are known to be useful in a composition or dosage and a method of treating pain. Moreover, muscle relaxants such as pridinol are well known to be useful alone or in combination with conventional analgesics for the treatment of pain. Therefore, one of ordinary skill in the art would have reasonably expected that combining a COX-II inhibitor such as rofecoxib and a muscle relaxant such as pridinol known useful for the same purpose in a composition to be administered would improve the therapeutic effect for treating pain, absent evidence to the contrary.

The declaration of Ethel C. Feleder is insufficient to establish the fact that the claimed combination has any unexpected synergism since the declaration lacks any

factual evidence for the synergism produced by the instant combination. The examiner agrees with Dr. Feleder that the discovery or expectation of a synergistic analgesic effect from a combination of analgesic drugs or drug classes is unpredictable. However, the record contains no clear and convincing evidence of unexpected results or unexpected synergistic analgesic effect produced by the combination herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 5, 2002

MINNA MOEZIE, J.D.
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